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Oystein Gomo

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EXAMINER

FLETCHER, JERRY-DARYL

ART UNIT

PAPER NUMBER

3715

MAIL DATE

DELIVERY MODE

08/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,306	Applicant(s) GOMO, OYSTEIN	
	Examiner JERRY-DARYL FLETCHER	Art Unit 3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following Office Action is in response to communications received on 07/06/2009. Claim 4 has been amended and the other claims have remained as previously presented. Claims 1-4 and 7-14 are pending in the current application and are addressed below.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/06/2009 has been entered.

Response to Amendment

3. Applicant's amendments to the drawings are insufficient to overcome the objections set forth with respect to the drawings in the previous Office Action. Specifically, the figures still contain shading, which is improper. The objection to the drawings is maintained.

Drawings

4. The drawings are objected to because they contain improper shading. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No: US 5,779,484 to Lampotang et al. (Lampotang), in view of US Patent No: US 3,662,076 to Gordon et al. (Gordon).

In reference to Claims 1-2

Lampotang teaches a medical patient simulator comprising:
a torso containing at least one artificial lung (col. 6, ll. 23-32) and a sternum (Figure 9, element 818); and
a chest skin placed at least partially on the outside of the torso (col. 26, ll. 41-44), and further teaches that a pneumatic mechanism is used for causing motion (col. 16, ll. 42-26).

Lampotang, however, fails to specifically teach a means for pulling down the chest skin providing an external visible depression of the skin below the sternum of the torso; or where the means includes a mechanism adapted to pull the chest skin in a synchronous fashion with the at least one lung raising and lowering the chest; or that the chest skin has an elastic pulling strap attached to the inside of the skin approximately in the middle of the area where contractions occur [claim 2].

Gordon teaches a patient simulator wherein the skin is moved to simulate breathing (col. 4, ll. 49-60 & col. 7, ll. 11-13).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have supplemented the invention of Lampotang by including the ability to simulate the movement of skin due to breathing, as taught by Gordon, to provide a more realistic simulator.

By using the elastic pulling strap as claimed by the applicant in claim 2 or by using the assembly taught by Gordon, the torso is able to simulate the movement of the skin due to breathing. The applicant has failed to suggest any special utility that the elastic pulling strap possesses over the invention of Gordon, and as such, it is interpreted as a matter of design choice to use either the apparatus as claimed by the applicant or the invention of Gordon.

At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art, to have used either the apparatus as claimed by the applicant or the invention of Gordon since it is interpreted as a matter of design choice that fails to patentably distinguish the claimed invention from the prior art of record [claim 2].

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang and Gordon as applied to claims 1-2 above, and further in view of US Patent No: US 4,606,328 to Thoman (Thoman).

In reference to Claim 3

Lampotang and Gordon teach the limitations of claim 2 (see rejection of claim 2 above), but fail to specifically teach that the mechanism is a pneumatic mechanism.

Thoman teaches a simulator that uses a pneumatic mechanism to simulate the movements associated with breathing (col. 2, ll. 36-40 & col. 3, ll. 55-58).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have combined the teachings of Lampotang, Gordon and Thoman, to have

substituted the mechanism of Gordon with the pneumatic mechanism of Thoman since this represents a substitution of known components to achieve a desired result.

8. Claims 4, 9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang in view of US 4,932,879 to Ingenito et al. (Ingenito).

In reference to Claims 4, 12

Lampotang teaches a medical patient simulator comprising:

a torso containing at least one lung (col. 6, ll. 23-32), with the option of altering the compliance of the at least one lung (col. 30, ll. 34-37), where the at least one lung is arranged between a first and second plate in the torso, the spacing of the plates being adjustable, the first plate being movable;

a pneumatically driven mechanism being adapted to force the first plate towards the second plate, the pneumatically driven mechanism including bellows (col. 16, ll. 42-46); and

a means for connecting the pneumatically driven mechanism to the second plate to provide the force between the first and second plate (col. 16, ll. 40-42).

Lampotang, however, fails to specifically teach that the means for connecting the pneumatically driven mechanism to the second plate is a flexible means wherein the flexible means is an elastic strap [claim 12], or that one of the plates is fixed [claim 4].

Ingenito teaches a training manikin wherein a lung is disposed between a first and second plate in a torso, with the first plate being moveable relative to the torso, and

the second plate being fixed relative to the torso (col. 14, ll. 53-68 to col. 15, ll. 1-2; Figures 7A, 7B) [claim 4].

The applicant admits that it is old and well known to use flexible and rigid connectors to transfer force from one body to another.

By using the claimed flexible means or the rigid means as taught by Lampotang, the effect of providing the force between the plates is accomplished. It is therefore interpreted as a matter of design choice to use either option over the other since they both achieve the same desired result, as claimed by the applicant.

At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art, to have used either the flexible means as claimed by the applicant or the rigid means as taught by Lampotang since the choice of one over another is interpreted as a matter of design choice that fails to patentably distinguish the claimed invention from the prior art of Lampotang. Furthermore, by supplementing the teaching of Lampotang with a plate structure similar to the one taught by Ingenito, the base of the bellows would be situated on a fixed plate, and the top plate of Lampotang would be the moveable plate. Additionally, as explained with reference to claim 1, the process of pushing upwards to simulate the motion of the lung has been interpreted to read on the applicant's claimed pulling of the chest skin (see design choice rationale in claim 1), and as such, the motion of the bellows in Lampotang is viewed as being patentably equivalent to the claimed recitation of moving the first movable plate towards the second fixed plate. In either scenario, the movement causes

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the compression and expansion of the chest, simulating the expansion and contraction of the lungs.

In reference to Claims 11 & 13

The claimed invention recited in claims 11 and 13 are not patentably distinguishable from the claimed invention of claim 4 since in claim 13, the applicant clarifies that the "third and fourth plates" recited in claim 11, are the "first and second plates" recited in claim 4. For this reason, the examiner rejects the claims under the prior art applied to claim 4.

9. Claims 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang in view of US Patent No: US 4,318,399 to Berndtsson (Berndtsson).

In reference to Claims 9 & 14

Lampotang teach a system for controlling different pneumatic functions in a patient simulator, the system comprising:

measuring a pressure which is representative for each individual actuator (a means for actuating the bellows between expand and contracted states depending upon a time- and event-based script) (col. 5, lines 33-35) and stopping the filling when a pre-determined pressure is reached;

using a pressure sensor (a pressure sensor situated inside the bellow) (col. 5, lines 52-53) for measuring the representative pressure, and a nozzle (a least one mass flow controller capable of directing the gas into the bellows) (col. 5 lines 38-39) being

disposed upstream of the pressure sensor for neutralizing the pressure difference between the pressure sensor and the actuator.

Lampotang fails to specifically teach that the pressure sensor is arranged in a branch line and located a distance from the actuator [claim 14], but rather teaches that it is in the bellows.

Berndtsson teaches the use of a pressure sensor that is connected a distance away from an actuator in a branch line assembly (col. 2, ll. 42-51) [claim 14].

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have supplemented the teachings of Lampotang with those of Berndtsson by substituting the pressure sensor arrangement of Lampotang with that of Berndtsson in order to use a branch line assembly. This represents a substitution of known elements to achieve a common result, that is, the measuring of the pressure.

10. Claim 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang in view of US Patent No: US 5,394,766 to Johnson et al. (Johnson) and US Patent No: US 6,336,047 to Thu et al. (Thu).

In reference to Claims 7-8

Lampotang teaches a medical patient simulator comprising a torso (Figure 1) but fails to specifically teach that the torso also includes two air cushion actuators [claim 8] arranged on the right and left sides of the backside of the torso wherein the actuators are designed to be operated in at least a mode for simulation of normal muscle movement, alternate and regular activation of the simulators on the left and right sides;

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a mode for simulation of muscle spasms, rapid and irregular activation of the actuators on the left and right sides; or a mode for simulation of defibrillation, rapid activation of the actuators simultaneously, once for each defibrillation.

Johnson teaches the use of actuators on the left and right sides of the torso of a simulated patient ((Figure 1, elements 50 and 50').

Thu teaches the use of a manikin to simulate spasms, breathing and defibrillation (col. 3, ll. 23-40).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have combined the teachings of Lampotang, Johnson and Thu, to have used the actuators of Johnson to simulate the movements taught by Thu in a patient simulator as taught by Lampotang. This would constitute the combination of known components to achieve a desired result since, as taught by Johnson, the use of actuators in dummies is known, and as taught by Thu, the use of dummies/manikins to simulate motion is known.

The applicant admits that it is old and well known in the art to use air cushion actuators.

By using air cushion actuators as claimed by the applicant in claim 8, or by using actuators as taught by the modified reference of Lampotang, Johnson and Thu, the effect of simulating the muscular motion is accomplished. Therefore, it is interpreted as a matter of design choice to choose to use the actuator assembly as claimed or the one taught by the modified reference of Lampotang, Johnson and Thu since the choice of using one over the other does not provide any significant utility.

At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art, to have used either the actuators as claimed by the applicant or the ones as taught by the modified reference of Lampotang, Johnson and Thu since the choice of one of the other is interpreted as a matter of design choice that fails to patentably distinguish the claimed invention from the prior art of record [claim 8].

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang in view of US Patent No: US 4,003,141 to Le Roy (Le Roy) and US Patent Application No: US 2004/0157199 to Eggert et al. (Eggert).

In reference to Claim 10

Lampotang teaches a medical patient simulator, in particular a simulator for simulation of an infant, comprising a head (Figure 1). Lampotang, however, fails to specifically teach a head having one or more air cushions in at least one fontanelle area on the head of the simulator, which air cushion(s) is/are designed to be filled with air in order to simulate an increased pressure in the brain and provide swelling in the fontanelle area.

Le Roy teaches an intracranial pressure monitoring device where a head has one or more air cushions (abnormal pressure creating means 30) (col. 4, line 7) also see (fig.2, element 30) in at least one fontanelle area on the head of the simulator, which air cushion(s) is/are designed to be filled with air in order to simulate an increased pressure

in the brain (the supply of air or other suitable fluid through tube 36 creates a pressure in member 38) (col. 4, lines 16-17).

Eggert teaches the use of a manikin to simulate swelling (par. 0128).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have combined the teachings of Lampotang, Le Roy and Eggert, to have provided a head having one or more air cushions in at least one fontanelle area on the head of the simulator, which air cushion(s) is/are designed to be filled with air in order to simulate an increased pressure in the brain as taught by Le Roy for the purpose of enhancing the apparatus of Lampotang et al. for a more accurate simulation of the dynamic condition occurring in the body during a traumatic occurrence. Furthermore, by using the manikin to indicate swelling, as taught by Eggert, the swelling of the fontanelle region can also be added to the invention in order to provide a realistic simulation with a graphic depiction of a swollen fontanelle area.

Response to Arguments

12. In the prior Office Action, the examiner took **OFFICIAL NOTICE** that:
- a. it is old and well known to use flexible and rigid connectors to transfer force from one body to another
 - b. it is old and well known in the art to use air cushion actuators

Applicant failed to properly challenge the statements of **OFFICIAL NOTICE** that were taken, and as such, they have become admitted prior art under MPEP 2144.03 C, which states, " To adequately traverse such a finding, an applicant must specifically

point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241 ("[I]n the absence of any demand by appellant for the examiner to produce authority for his statement, we will not consider this contention."). A general allegation that the claims define a patentable invention without any reference to the examiner's assertion of official notice would be inadequate. If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR 1.104(c)(2). See also *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test). If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2). If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate."

13. Applicant's arguments filed 07/06/2009 have been fully considered but they are not persuasive. Specifically, with respect to the arguments directed to claims 1-2, the applicant argues that the prior art of Lampotang and Gordon both fail to teach that the chest skin is pulled down. The applied prior art of Lampotang and Gordon provide an equivalent structure to the applicant's claimed invention. The function of simulating the raising and lowering of the chest with a lung is achieved by the Lampotang-Gordon prior art, as well as with the applicant's claimed means-plus-function limitation. Secondly, there is no explicit definition provided in the applicant's specification that debars the use of the prior art, with the applicant disclosing several methods for achieving the function of simulating chest retractions on page 1, ll. 17-32 to page 2, ll. 1-32 of the specification. One of ordinary skill in the art would recognize the interchangeability of the skin movement mechanism of Lampotang-Gordon, and the claimed invention to produce skin movements reflective of chest retractions.

Applicant's arguments with respect to claim 4 have been considered but are moot in view of the new ground(s) of rejection. Specifically, newly applied prior art of Ingenito, when combined with Lampotang, teaches the claimed invention, as shown in the rejection of the claim above.

Applicant's arguments with respect to claims 9 and 14 have been considered but are moot in view of the new ground(s) of rejection. Specifically, newly applied prior art of Berndtsson, when combined with Lampotang, teaches the claimed invention, as shown in the rejection of the claims above.

With regards to applicant's arguments directed to claims 7 and 8, it is noted that the actuators of Johnson are indeed located at the back of the torso (see Johnson, Figures 4-8). Furthermore, Thu teaches the use of manikins to simulate muscle movement, and as such, it would be obvious to one of ordinary skill in the art to use a manikin, such as the one taught by Johnson, to simulate muscle movement. In response to applicant's argument that the air cushions could not be incorporated into the prior art of Lampotang-Johnson, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant's arguments with respect to claim 10 have been considered but are not persuasive. The greater fontanelle area is depicted in applicant's Figure 5, but is never defined in applicant's specification. The greater fontanelle area is known to those of ordinary skill in the art as the area on an infant's skull where the two frontal and the two parietal bones join. In the prior art of Le Roy, Figure 4 depicts several areas of abnormal pressure, with reference numeral 46 in essentially the same region as the greater fontanelle.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY-DARYL FLETCHER whose telephone number is

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(571)270-5054. The examiner can normally be reached on Monday to Friday 9:00 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan M. Thai can be reached on (571) 272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kathleen Mosser/
Primary Examiner, Art Unit 3715

/J.D.F./
Examiner, Art Unit 3715